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Dear Dr. DeSalvo:

Congratulations on the release of the draft nationwide interoperability roadmap, “Connected Health and Care for the Nation.” The Healthcare Leadership Council applauds the work of the Department of Health and Human Services (HHS) and the Office of the National Coordinator (ONC) for Health Information Technology for your work on our shared priority of a fully interoperating health system. We believe that, by bringing together the ideas and technological expertise from both the public and private sectors, interoperability is a foreseeable and achievable goal.

The benefits to patients and the future of American healthcare in achieving full interoperability are enormous. A system built on accessible information and secure, meaningful data sharing will elevate healthcare delivery, advance quality and cost-efficiency, and enable new strides in medical research.

The Healthcare Leadership Council (HLC), a coalition of chief executives from all disciplines within American healthcare, is the exclusive forum for the nation’s healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC—hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, pharmacies, and information technology companies—envision a quality-driven system that fosters innovation. HLC members advocate measures to increase the quality and efficiency of American healthcare by emphasizing wellness and prevention, care coordination, and the use of evidence-based medicine, while utilizing consumer choice and competition to enhance value.

HLC CEOs, who are leaders in every healthcare field, have agreed on the need for an interoperable health IT infrastructure constructed in a way that is both beneficial to

consumers and realistic and sustainable for industry. Building upon these recommendations, HLC members have continued to work toward our shared goal of active health information exchange—among all health sectors. We will continue to support and guide the work of Congress, the administration, and other organizations working to create the health system of the future. Each of our CEO members agrees that:

- Policymakers should **encourage exchange of material and meaningful health data** through the use of technologies and applications that enable bidirectional and real-time exchange of health data currently residing in electronic health record (EHR) systems (e.g., open and secure API technology).
- Policymakers should use appropriate authority to **certify only those EHR technology products that do not block or otherwise inhibit health information exchange**. The HHS Office of the National Coordinator should decertify “Meaningful Use” products that intentionally block the sharing of information, or that create structural, technical, or financial impediments or disincentives to the sharing of information.
- The federal government, in collaboration with the private sector, should **build on current and emerging best practices in patient identification and matching** to identify solutions to ensure the accuracy of every patient’s identity, and the availability and accessibility of their information, absent lengthy and costly efforts, wherever and whenever care is needed.
- Any interoperability **requirements or incentives should be “technology neutral” and focused on outcomes** – active interoperation between and among systems—rather than on adoption or use of specified technologies. It is critical that future policies do not stifle potential innovations in health system connectivity.

Specific to ONC’s draft interoperability roadmap, “Connecting Health and Care for the Nation,” HLC has identified several areas in which we believe our multisector experience can provide useful guidance for ONC. We expound upon these areas below, after providing broader commentary on the plan and our shared goals.

BROAD COMMENTS

HLC is pleased by the broad view of our shared interoperability challenge outlined by ONC in the draft roadmap. The effective interoperation of health information requires

more than a technical fix—and more than a simple ban on “blocking.” It requires an alignment of incentives, a systematic approach to addressing the many barriers to an interoperating and learning health system, and a continued focus on the consumer experience. Not all of these issues can be addressed by ONC, but acknowledgment and prioritization of those issues that we must address will allow ONC and Congress (when appropriate) to drive progress in tandem with the accelerating efforts of the private sector.

HLC is also supportive of ONC’s described intent to “build upon existing health IT infrastructure” and “maintain modularity.” While HLC members appreciate the need for government leadership in some limited areas, we encourage ONC efforts on standards and principles retain an approach of providing minimum necessary governance to achieve a desired outcome. Momentum in the private sector is already swinging toward interoperability—it is important that overregulation does not impede innovation and experimentation in the marketplace.

HLC strongly encourages a continued focus on outcomes-based approaches to measuring progress in interoperability (rather than just standards). The ability to exchange health information is not necessarily the same as actual interoperation—patient and provider-authorized information exchange—between and among the many disparate health IT platforms in use today and in the future. A role for the federal government is needed to encourage the development and use of standards in certain key areas including patient identifiers, terminologies, clinical data query language, security, open application program interface criteria, and clinical decision support algorithms, among others.

Priority Use Cases

ONC has requested guidance on the prioritization of use cases provided through public comment, listening sessions, and federal agency discussions. In the context of our previous comments, several of these use cases are foundational to an effectively functioning and learning health system and should guide the prioritization of efforts to promote interoperation:

- *Care Coordination / Patient Centered Interoperability:* The primary goal of interoperability must always be the positive patient experience. Individuals directly in contact with the patient or the patient’s health information must be able to share relevant information with one another as well as the patient, regardless of geographic location or healthcare setting. This information sharing needs to be both timely and bidirectional. Interoperation also needs to be expansive—

included in this connectivity should be the health information systems of providers, pharmacists, payers, IT connected medical devices, laboratories, and other ancillary services providers—when appropriate. Through this coordination, the patient experience will be improved, medical errors will be reduced, and illness better prevented.

- *Value-Based Payment:* As initiatives by private sector organizations, HHS, and Congress accelerate our shift from fee-for-service to value-based payment, payers must have access to relevant clinical data to support payment reform and providers must have a complete picture of patients entrusted to their care. Broader interoperability and integration between organizations has the potential to expand the potential and appeal of alternative payment models such as ACOs.
- *Quality Measures:* Effective interoperability among information-holding entities is critical for the alignment of measures across various government and private sector programs. HLC supports efforts to streamline quality measures to focus on a small, limited core set of quality measures to reduce data collection costs and administrative burden for providers and payers. These measures should be outcome-focused (rather than “process” measures) endorsed by a consensus body, and aligned across health organizations and systems. Interoperability among systems is necessary for these measures to capture data proving the efficacy and long-term value of interventions on patient outcomes.
- *Clinical and Claims Data Sharing for Research:* Interoperability of clinical data has the potential to accelerate the learning health system by orders of magnitude. Interoperability could substantially lower the barrier of entry to comparative effectiveness research using large, real-time datasets. Legal and confidentiality issues must continue to be taken into account when using clinical data; however, interoperating systems using a common clinical data set could significantly lower technical barriers to this type of research. Academic medical centers, pharmaceutical and device manufacturers, payers, and others could benefit from expanded clinical data access through interoperability.
- *Telehealth and Remote Patient Monitoring:* One of the most important outcomes of an interoperational system should be the increased ability to utilize telehealth and remote patient monitoring (RPM) throughout the care system. This will enable better care to be provided, particularly in rural or underserved areas, at a lower cost, while still maintaining care coordination among multiple providers. The use cases related to telemedicine should be considered when working on other areas of the roadmap, because the success of telehealth will depend

largely on the roadway it can travel on (in addition to lifting regulatory barriers, which currently stymie wider adoption of telehealth).

- *Wellness and Prevention:* Interoperation can provide the basis for dramatic steps toward improving the wellness of all consumers and patients. At a population health level, it would allow for better disease detection and surveillance, which would inform both clinical responses as well as scientific advances. At a patient level, interoperation would lay the groundwork for better coordination between the patient and the provider. For example, in the pharmacy setting, this would improve the ability for providers to perform comprehensive medication management (CMM). Expanded use of CMM would promote medication adherence, which in turn would improve health outcomes while lowering health costs for the patient as well as the healthcare system. Interoperation would also enable labs, tests, and other inputs to be more rapidly and comprehensively shared with providers at the decision point of care. Finally, interoperation has the potential to allow the health system to incorporate patient-generated data and RPM data so care providers of all types can make better informed decisions with their patients.

Barriers to Interoperability

Having discussed some top priorities that would be accelerated or enabled by interoperation, we also believe it prudent to list some of the top barriers – including conflicting and burdensome state laws governing health information, intentional and unintentional information blocking, misalignment of incentives in other government programs, and patient identity matching. HLC believes the federal government has a unique role and capability to address some of the longstanding and significant barriers undermining private sector efforts to facilitate interoperation. The resolution of these barriers would represent significant steps toward allowing the private sector to increase interoperability and health information exchange.

One of the most significant barriers to interoperation, as mentioned previously, is the intentional blocking, slowing, or excessive cost of information transfer created by those seeking to use health information for competitive advantage. Policymakers should use appropriate authority to ensure that providers and technology vendors do not block or otherwise inhibit health information exchange. ONC should, within one year, develop metrics to measure the exchange of health information and take appropriate steps to penalize those that are not acting in the greater interest of the patient. As discussed in further detail below, penalties would need to be cognizant of real-world implementation constraints.

The lack of a nationwide strategy for matching patients to their electronic health records is a major impediment to accurate, inexpensive, secure, and timely transfer of electronic health records. HLC applauds ONC's previous work on patient matching, but emphasizes that this effort must be a key component of a successful interoperability roadmap.

HLC members have collected case studies from across our diverse membership exhibiting various barriers to health information exchange. While many of these align closely with the needs of the priority use cases described in the draft roadmap and this document, we have attached a selection of these case study responses for your use (Appendix A).

LEARNING HEALTH SYSTEM REQUIREMENTS

Rules of Engagement and Governance

A. Shared governance of policy and standards that enable interoperability: Nationwide interoperability across the diverse health IT ecosystem will require stakeholders to make collective decisions between competing policies, strategies, standards in a manner that does not limit competition. Maintaining interoperability once established will also require ongoing coordination and collaborative decision-making about change.

HLC appreciates ONC's acknowledgement of the private sector information governance entities that have emerged in response to the nationwide need for improved health information interoperation. HLC also recognizes the need for the federal government to help better align incentives for these organizations to work together. HLC strongly supports the assertion that no policy, business, operational, or technical barriers should prevent the flow of information. Any and all requirements for interoperability should be designed to set a "floor" for information exchange and should not prohibit health organizations from finding new and innovative ways to improve interoperation.

Restricting access to health data should not be used to create a competitive advantage in the marketplace. HLC supports a definition of interoperability that encourages technologies to be open to external electronic queries and patient matching/record location and securely provide relevant health information to healthcare providers for a reasonable cost, in a timely manner, and in an accessible format.

All health information exchange should be either provided without cost or priced at a fair market value. Recognizing that exchanging information carries a cost (in dollars or

infrastructure investment), we do not advocate that health information exchange should always be “free.” We believe that health information should be provided in a way that does not discourage access, as other non-clinical transactions are funded today. Pricing for access interfaces and data should be nondiscriminatory – price should not be used to create a competitive advantage and therefore a barrier to health information exchange.

HLC supports a role for ONC in convening stakeholders to create interoperability standards and patient-centered outcome measures. A private-public partnership on HIT interoperability governance should be established in collaboration with ONC and in coordination with other federal agencies. This partnership should develop and implement a nationwide interoperability governance framework that leverages the ongoing work of the private sector to achieve interoperability. The body should have three branches with separate core functions: 1) a body charged with the adoption of technical and interchange standards for technologies, 2) a body charged with the adoption of common clinical terminologies, and 3) a body charged with removing regulatory and legal barriers to the practical implementation of the standards. Policy considerations should include development, navigation, and deployment of items such as a national consent model. This private-public partnership must include representation from diverse stakeholders including patients, providers, and payers, as well as national advocacy organizations, patient groups, EHR vendors, third-party vendors that build applications that integrate with EHRs, software developers, standards development organizations, and key government health programs. This entity should be committed to leveraging market forces so as to ensure that exchange is based on realistic and sustainable business models.

ONC, through its certification program, should also have an ongoing role in a public/private sector enforcement mechanism for interoperability. This interoperability attestation should be required of vendors of EHRs in addition to their customers. Further, the private-public partnership should have the option to expand interoperability requirements to other systems, as deemed appropriate by the consensus of the public and private sector experts. These interoperability outcome measures should be validated and tested in terms of standards, processes, and within specific use case scenarios to capture the complexity of EHR systems and should include cost/efficiency metrics to determine whether cost creates barriers to information access. Additionally, ONC should require any certified EHR product to provide the ability for patient records to be extracted into a standard format and loaded into another system, to prevent technical barriers to information transfer.

While we support the inclusion of possible decertification as a tool, any approaches to decertification in the future must include timely due process, appeal processes, as well as enforcement. We also recognize and support the need for some sort of protection or support for providers or other purchasers of electronic health record systems unexpectedly penalized by changes to electronic information sharing rules.

Supportive business, clinical, cultural, and regulatory environments:

B. A supportive business and regulatory environment that encourages interoperability: Rules that govern how health and care is paid for must create a context in which interoperability is not just philanthropic, but is a good business decision.

There are numerous existing federal programs, initiatives, incentives, penalties and payment rules related to health IT but they are fragmented or inconsistent in their approach to health IT interoperability. The Secretary of HHS should collaborate with other agencies to take such steps as are necessary to align and identify gaps in all existing federal programs to adopt the comprehensive definition of health IT interoperability.

HLC strongly encourages HHS to align of Centers for Medicare and Medicaid Services (CMS) and other federal payers with interoperability outcome goals. It is important that payment align with best practices in health IT interoperability in order to accelerate and simplify the expansion of health information exchange. This is critical both because of the large footprint of CMS and because of its influence on other payment systems, including private payers.

As long as fee-for-service remains the predominant reimbursement model, it is difficult to justify the significant initiation and ongoing investment required to maintain a health information organization. As these payment models shift to a risk-managed population model, sharable, consumable data will be essential to support an entirely new set of use cases. At that point, a true return on investment for interoperability will become measurable and justifiable.

HLC recognizes that value-based payment models are already incentivizing greater information sharing within parts of the healthcare system. The ongoing shift to outcome-based payment could play an important role in driving the changes necessary in the system – particularly if performance measures incorporate information sharing. ONC should take care to monitor and evaluate progress as the roadmap progresses, and withdraw further requirements if they prove unnecessary.

Further, as previously mentioned, there may be instances in which it is appropriate for reasonable fees to be applied to health information exchange. Assuming that such a fee did not benefit one sector of healthcare at the expense of another, these fees may enable greater information flow—leading to better patient outcomes. HLC strongly believes that costs should never inhibit patient care and supports the use of cost and efficiency metrics to determine whether cost creates barriers to access.

Privacy and security protections for health information

G. Consistent representation of permission to collect, share, and use identifiable health information: Though legal requirements differ across the states, nationwide interoperability requires a consistent way to represent an individual's permission to share their electronic health information, including with whom and for what purpose(s).

H. Consistent representation of authorization to access health information: When coupled with identity verification, this allows consistent decisions to be made by systems about access to electronic health information.

Public trust in the use and transfer of electronic health information is crucial to the effective use of this information to improve the healthcare system. It is particularly necessary to encourage the inclusion of patient-generated data in the health system. Clarity of rules and regulations governing health data are also critical to the transfer of this information. Ambiguity around privacy and security requirements, conflicting roles and regulations, and overly complex consent forms have contributed to inappropriate refusals to exchange or disclose needed healthcare information.

One particularly burdensome barrier to nationwide health information exchange are the many diverse state laws across the country regulating health information. HLC and its affiliated Confidentiality Coalition have long advocated for the harmonization of national privacy and security requirements. We are very pleased to see ONC outline a path forward for harmonization of conflicting, confusing, and burdensome state privacy laws. These laws create enormous complexity resulting in substantial impediments to the implementation of health information exchanges within and across state borders. We believe that a broader preemption that would clearly incorporate the Health Insurance Portability and Accountability Act (HIPAA) governing standards would benefit the health care system without creating any material adverse impact on individuals.

We support ONC efforts to educate states on existing federal standards and begin a dialogue on this important problem. With regard to the critical actions outlined in the roadmap, we believe there is both precedent and will for an accelerated timeline with

stakeholders acting alongside ONC. Specifically, a discussion with nationwide stakeholders should include possible action items, such as harmonization of state and federal law.

One instructive example in this area is the state of Hawaii which passed legislation in 2012 (HB 1957) harmonizing more than 50 existing privacy laws in the state related to the sharing of personal health records between providers to comply with HIPAA national standard. It is our understanding that this law was promoted by a local health information exchange (HIE). The law's goal was to streamline compliance, and as a result, reduce errors and duplicative procedures, improve care, and ensure that providers can share health data without worrying about being in compliance with numerous and sometimes inconsistent federal and state laws. Discussion of this approach does not need to wait until the 2018-2020 stage of the roadmap and should be part of any conversation with state-level stakeholders or associations in the near future.

Conclusion

Thank you for the opportunity to provide comment on ONC's draft interoperability roadmap. We look forward to ONC continuing to work alongside the private sector in order to ensure the successful implementation of a nationwide, interoperating health network that includes all necessary components of the healthcare system. If you have any questions, please feel free to contact HLC's Senior Vice President for Policy, Tina Grande, at tgrande@hlc.org.

Sincerely,

A handwritten signature in cursive script, reading "Mary R. Grealy".

Mary R. Grealy
President



Barriers to Health Information Exchange: Illustrative Case Studies

The Healthcare Leadership Council (HLC) has long served as the innovative voice of healthcare in the United States. HLC CEOs, who are leaders in every healthcare field, have agreed upon the need for an interoperable health IT infrastructure that is both beneficial to consumers and workable for industry.

As federal policymakers address the issue of interoperability, Congress has articulated a desire to prevent the “blocking” of health information exchange. In the Fiscal Year 2015 appropriations report language, it urged the Office of the National Coordinator for HIT (ONC) to *“use its authority to certify only those products that clearly ... do not block health information exchange. ONC should take steps to decertify products that proactively block the sharing of information.”*

In order to educate this discussion, HLC has collected anonymous case studies from its members across the healthcare industry and included them below. These examples describe a specific instance in which the interoperation of electronic health information is hindered or “blocked.” It is important to note that the barriers to information sharing are often not intentional or malicious, but that they do exist throughout the health system. These examples include financial challenges, technical challenges, and other problems that prohibit or reduce productive information exchange.

We offer several high-level takeaways from these case studies:

- The barriers to information exchange are complex and not easily overcome. While many of us aspire to an interoperating health system using shared data to accelerate progress in medicines, technologies, and healthcare delivery, the problem is much more complex than a simple “blocking” issue. The solution to this problem will also be much more nuanced than a simple prohibition.
- Defining the goal properly matters. Past views of interoperability have included the capability of connecting information from one point to another. Instead, interoperability must be defined by a patient-centered outcome. Electronic health

information must interoperate so that a patient entering any part of the health system is followed by their health information. In this context, any barrier to that interoperation – be it financial, technical, or legal – must be overcome.

- Despite frustration with the current state of interoperation, significant progress has been made over the past several years. Initiatives led by the private sector, alongside collaborative health information exchanges, have resulted in significant progress towards creating a foundation for true interoperability.

Examples of Barriers to Information Exchange:

(Case studies last updated March 20, 2015)

- There is an oncology vendor that has a very good stand-alone system but lacks any expertise in interoperability. This lack of knowledge has made it impossible for our oncologists to be MU qualified. The vendor specifies that they are MU certified for order entry only so they do not offer any real way to get clinical summaries out of their system, which prevents a true care plan. The only option offered was saving word documents to a file location and then for us to write a screen scraping program to pull the information from word. The lack of options from the vendor required us to get creative with our integrations and operations staff, the costs to keep the systems in sync through a combination of manual and automated approaches was over \$500,000.
- Despite major EMR vendors touting advanced interoperability, they still only allow a plain text outbound document interface from their EMR system. If you license another module, you can get PDF but that is not a real-time feed. I would expect these vendors to offer real-time PDF as well as XML so that formatting can be maintained and structured content can be accessible.
- A health IT vendor operates on an open platform and routinely interfaces with competitors' technology at no cost to our clients. They experience 'information-blocking' in a very specific and very common way. To be clear, first, to our knowledge nobody in the marketplace is literally "blocking" information sharing in healthcare. There are no contractual provisions that say, "you cannot share information outside of our platform." Moreover, there are no firewalls built to contain information. Many dominant health IT vendors, however, routinely create technological and/or financial impediments to the easy and routine sharing of information across and among disparate vendor platforms. These vendors then use those impediments to create a competitive advantage in the marketplace.

The proposition is "if all of the providers in a referral community get on our platform, coordination of care will be easy. If they don't, well, we are going to charge significant interface and/or transaction fees to enable information-sharing." As a result, their clients do not routinely share information outside of their networks, because it is deliberately difficult and/or costly to do so. In particularly egregious cases (which are not uncommon, in our experience) care providers are implicitly or even explicitly threatened with a loss of access to a referral network if they complain about or otherwise resist pressure to get on a specific EHR platform. That kind of anti-competitive behavior aside, in our view closed systems remain a legitimate business model, apparently serving a legitimate ongoing market demand for closed information networks in healthcare. However, if the government's goal is data fluidity and broad care coordination in healthcare, then government should not be incentivizing use of such systems, financially or otherwise.

- Example 1: A family medicine practitioner who has been on our system for years and is very happy with it is under extreme pressure from the hospital with which he affiliates to switch to the EHR chosen by that hospital, because that hospital's vendor would impose significant interface and per-transaction fees to enable information sharing between the two platforms. As a result, this doctor pays a staffer specifically to do double entry of patient records into the hospital's system and into ours, (which he has determined better serves his practice and his patients). This is inefficient, adds costs, and vastly increases the chance for errors in patient records, all to the detriment of the practice and its patients.
- Example 2: a mid-sized doctors' group is a long time client of ours and is very happy with our EHR and other services. The local hospital from which the practice gets the majority of its referrals recently switched to a vendor that imposes significant interface and per-transaction costs for sharing of information outside of its platform. The practice has come under intense pressure to switch, which in the care providers' view would negatively affect the practice and its patients. The practice was initially given three options: (1) switch to the hospital-chosen EHR, in which case the hospital would heavily-subsidize the switch; (2) have the hospital's vendor build a "limited interface" to the practice's EHR, the cost of which would be completely borne by the practice; or (3) leave the hospital's referral network and contracts. The practice chose option (2) and was immediately told that option (2) was no longer "on the table." It was an all-

or-nothing proposition: make the switch, or lose the referrals.

- Example 3: It is quite common for vendors that do in theory enable "information sharing" outside of its platform to make such sharing functionally infeasible, if not impossible. One way of doing that is not "information blocking" so much as tight information control. Therefore, for example, a drop-down list of possible referral recipients will either 'bury' the names of providers outside of the vendor's own network, or will exclude them entirely. This is a very common scenario that we view as a functional--if not literal--example of information blocking for purposes of this analysis.
- There are instances when health plans design customized messages to send to the dispensing pharmacy informing the pharmacists of formulary alternatives, PA requirements, or other special instructions and the pharmacy chain elects to block or hide these messages in lieu of their own. This can cause member disruption by either not being able to get their Rx filled in a timely manner or paying a higher amount than they should.
- From the perspective of being a large hospital that both (a) has "tight" business partners, for example faculty practice organizations with whom we share patients and exchange data, and (b) participates in regional data exchange activities through our local "RHIO". The local Regional Health Information Organization (RHIO) includes multiple academic medical centers, other hospitals, non-acute facilities, private physician offices, other care provider, and social service organizations.
- From the perspective of being a large hospital, one of the biggest hurdles to exchange of data is the hesitancy of providers to participate in exchange. The hesitancy is related to such issues as (a) the fear of losing patients to competitors because competitors will now have easy access to patients' clinical data, (b) concerns about other stakeholders – competitors, government – being able to scrutinize the organization's performance, (c) inappropriate uses of the data, such as marketing, and (d) concerns about breach-related liability. Some of the approaches that have been used to decrease the hesitancy include appropriate governance models, including appropriate data use agreements. Some of these concerns continue to be significant impediments to data exchange in our community.

- A Regional Health Information Organization (RHIO) in which my organization participates identified two EHR vendors that it has worked with where the vendor would release data if the vendor was queried by the RHIO; however, the vendor would not initiate the sending of the data to the RHIO at relevant times, e.g., at the “closeout” of the clinical encounter. This required the RHIO to either continually poll the EHR vendor’s system – which might create performance issues and possibly cost issues, if there is a per-transaction fee model – or force the RHIO to go without timely inclusion of that vendor’s data. The lack of timely data from EHR vendors is a significant problem because it inhibits accurate analytics and also real-time awareness of the patient’s state, which has relevance for understanding when patients are out of compliance with quality measures. I would note that for at least one of those vendors, recently, they have agreed that they would change their approach and, in fact, begin to initiate sending of data to the RHIO at relevant times; however, this has not yet been implemented.
- A Regional Health Information Organization (RHIO) stated that an EHR vendor did not put adequate controls on the consistency with which its various clients produced documents intended for exchange. This meant that anyone requesting data from this EHR vendor’s customers would see a hodge-podge of varying document formats. The inconsistency among the data formats makes the data that is returned almost completely unhelpful for clinical care. This problem could be solved through more effective use and implementation of document formatting standards.
- The Consolidated Clinical Document Architecture (CCDA) format is required for the summary of care at transitions requirement under meaningful use. The CCDA documents address transitions of care use cases reasonably well. However, the certified EHRs generate very comprehensive transitions of care documents that are often more than 50 pages. The volume of information included in these documents makes it very difficult for providers to find the critical, relevant information needed for patient care. Refinement is needed to support creation of more clinically relevant documents specific to the type of care transition being supported. Challenges:
 - More than fifty pages of summary of care documents lack clinical value to providers. An overly complicated process to try to standardize sub-data elements and break down data elements into fields for electronic transmission has distorted the value of a transition document – easily and quickly presenting relevant clinical data and reason for referral.

- We have experienced some physicians actually asking for their direct addresses to be removed from the system or shut down so they will stop receiving these CCDA documents.
 - This has caused considerable concerns on the part of the hospital/provider as they need to comply with the meaningful requirement but cannot afford to alienate their referring population either.
- Three Hospital Systems are using the same certified Patient Portal product with their acute care certified EHR from a different vendor. Both vendors are certified and have established their HISP. Despite being certified, these vendors had direct compatibility issues due to HISP-to-HISP security configuration issues. The cause of the interoperability challenges for both vendors included incompatible anchor and trust certificates (which are like the lock and key) and unsupported and non-standard encryption algorithm. Challenges:
 - The certification standards are so complex that even the vendors who are certified do not seem to possess all of the necessary functionality to work together to achieve interoperability.
 - The technical delays have continued to place the provider in the middle – facing a loss of incentive dollars and possible financial penalties. These types of roadblocks prevent providers from moving forward with meaningful use and active data sharing and it can take months for vendor-to-vendor issues to be resolved.
- A Hospital uses a different vendor EHR product in their physician practices than in their acute care facilities. The acute care facilities have met meaningful stage 2 and built a large repository of external provider names and direct addresses in the acute care EHR for electronically sending summary of care documents (a meaningful use requirement). The physician practices are able to electronically send and receive summary of care documents among the practices with their ambulatory EHR, but they are unable to send or receive clinical documentation with physician practices using a different EHR vendor. This problem occurs because the ambulatory EHR does not have a health information service provider (HISP) or a direct address for providers not using their EHR. A total of 618 ambulatory referrals were identified that could not be sent to providers that use a different ambulatory vendor EHR. To address this problem, the ambulatory vendor asked the Hospital to collect a Direct address and HISP for these providers and submit back to them to then add to the EHR. The Hospital System approached the vendor and requested to use the established repository within their acute care EHR to reduce the effort required to resolve the issue. However, the ambulatory vendor responded that this was outside their scope of

services and the burden of solving the issue falls on the Hospital System.

Challenge:

- The entire burden of achieving interoperability with providers using a different EHR platform falls to practice management staffs that are not staffed to handle this unbudgeted work.
 - Continues the cycle of creating alternate workflows and work-arounds to send summary of care documents to referring providers who are not on the same platform, despite having meaningful use certified EHR technology.
 - Further complicating the issue is that many receiving providers do not have the capability to receive documents sent using the direct protocol and many patients transition to nursing homes or rehab facilities that often do not have EHRs and if they do, they do not have EHRs embedded with the HL7 CCDA summary of care document standard.
- An ancillary services provider has maintained superb relations with large physician organizations based on great service and great innovation. However, when physician practices are acquired by hospitals they receive the hospital's EHR, which frequently is only interoperable with the institution's own ancillary services or with providers holding exclusionary contracts with the hospital. Building new interfaces requires significant cost and work. It becomes prohibitive when there is no business model to support the expense.

Not having those interfaces creates a suboptimal environment for patients and physicians. There are several clinical impacts that result from this behavior. Years' worth of critical patient data is no longer available either at the point of care or for analytics. This company has provided insights from trended ancillary data that has changed practice patterns among some of providers focused on population health such as Federally Qualified Health Centers. Positive outcomes include better results in diabetes and cost savings in anticoagulation therapies.

This type of information blocking interferes with value-based care, which functions optimally when data is available that can be trended to reveal health status and even has predictive potential. Information blocking drives up cost and reduces quality of care. Specific examples of the deleterious effect of information blocking:

- A company served a large HIV practice that was acquired by a major teaching hospital. When the hospital moved the practice to the system of a major vendor, the physicians could no longer get access to critical

history. Even worse, tightly controlled laboratory ordering regimes were disrupted for this vulnerable population.

- A municipal hospital acquired several women's health practices and moved them to a major vendor's EHR, locking them from a company's services. Yet this company had unique products in the women's health space that are less invasive than their competitor's products. The practices' clients were deprived from receiving those superior services.

Categorized by Type of Model

- State HIE and Provider EHR System Model: In this example, a provider is required to connect to a state health information exchange (HIE). The state HIE requires the provider push a Continuity of Care Document (CCD) for each patient visit to the HIE. The provider has an EHR and an associated HIE. The HIE captures the affiliated provider patient data in the form of a CCD or direct HL7 feeds, and aggregates and normalizes the data so that both the affiliated providers and the patient have a summary view or access to the detail CCD. The EHR vendor uses the HIE as its exchange broker to connect with other HIEs or providers for query and retrieval. In this situation, the state HIE required full exchange of the CCD and the EHR's HIE provided a record locator. Because the two services did not use the same exchange protocols, they were not compatible and the requested service could not be provided. Both the state's HIE and the provider found that supporting multiple protocols at that time was cost prohibitive.

This example demonstrates an unwillingness to support the outbound exchange of certain data sets by one participant and the required compliance to a non-government regulated standard (or protocol) by another participant. The lack of common exchange models has led to many different types of implementation. Efforts to develop, scale, and support multiple exchange models is very expensive and time consuming. Vendors typically select a model that they believe will provide the best service to their customers and one that will likely be pervasive in the market. As the market matures and standards evolve, a dominant model will emerge. Until that time, the exchange broker, whether it is the state HIE or the EHR's HIE, must either support multiple models, require conformance to its selected model or choose not to exchange with those services that use different protocols.

- Direct Exchange Model: Direct exchange requires a trust infrastructure to securely exchange email messages and attachments (C-CDAs). Each provider is assigned a certificate that establishes a level of trust based on a vetting

process. The degree of trust is dependent on how extensive the vetting process is for the organization's established protocol. Today, a specific level of established trust is not a mandated requirement. However, because of the nature of the information being exchanged and the need to trust or verify that the participant is communicating with the right entity, many organizations in the industry believe that the level of trust must be very high. For example, exchange protocols with a federal agency require the highest level of trust. If an organization attempts to exchange information with another organization with a higher or lower level of trust, the exchange will not be compatible and will fail. This exchange failure happens frequently.

In the Direct Exchange Model example, there is a required compliance to a non-government regulated standard or protocol by one of the participants. A Health Information Service Provider (HISP) that requires a higher level of trust than another could be accused of data blocking but in reality, the HISP has established a security level that they believe is necessary to assure a trusted exchange. Since there is no industry standard for the level of trust for direct exchange, lower levels of trust may be used because they are more economical and therefore, more appealing to smaller provider practices and smaller health IT vendors.

A HISP takes the direct message from the provider that they support and sends it to recipient via the HISP that supports the recipient. The HISPs must trust that they each conform to certain standards and operating procedures to securely exchange the message. This means that these participants either enter into a unique trust agreement with each other and establish a method for continued verification or that they affiliate with an association that establishes the baseline and certification criteria to assure a trusted exchange. Many HISPs that affiliate choose to limit exchange to those HISPs that have been certified through the same association. This practice reduces the cost of "one to one" verification and contracting and provides a high level of trust and confidence in the exchange service they provide their customers. However, this practice could be perceived as data blocking by an EHR and its customers whom use a HISP that is not a part of the association.

- Best of Breed Implementation Model: Providers often purchase best of breed solutions for specific areas of the enterprise, such as the emergency department, and request comprehensive integration between those best of breed systems and the EHR and the patient access systems including orders and registration. These are very costly and complex integration services because of the unique

data models, workflows and the inter-dependency of upstream and downstream systems. Many EHR vendors avoid providing more than the basic interfaces in order to minimize associated risks and their liability. Some vendors may offer to perform these complex integration services at a very high price, which is often a reflection of their resource capacity and preference to risk avoidance. In this example, the EHR vendor operates with narrowly defined subsets of information available for sharing, which could be perceived by some parties as blocking data.

- Proprietary Implementation Model: True data blocking occurs when a vendor's actions impede competition. Such examples occur when open standards are available but a large vendor requires conformance to their proprietary APIs for exchange. It becomes costly for smaller vendors to support these unique APIs and often the large vendor makes it easier for the customer to "just" replace the small vendor with their product than address the exchange services.

Additionally, pricing or business practices can create substantial barriers to the exchange data. Some vendors optimize the integration between their products and within its network often creating seamless exchange. This is good business. The vendor wants its products to work well together and to enable seamless exchange among its customers. The challenge is when the vendor optimizes the exchange services between its customers and provides very limited and/or cost prohibitive exchange services outside the network. If the vendor has significant market share in an area, this practice makes it difficult for providers to retain their existing vendors or select an alternative and successfully exchange with others in their community.

Proprietary APIs that are not generally available to all parties and pricing or business practices that create substantial barriers to exchange data are both examples of data blocking practices. Both the best of breed and proprietary models described above involve business and software implementation practices that impede open access to other vendor systems. These practices not only create a competitive disadvantage across some health IT systems but also block the flow of patient information where interoperability may be desired and needed for optimal patient care.